

# **EXHIBIT 16**

**All disputed ROGs in numerical order**

**ROGs 1-5, 7-8, 10-11, 13**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND	)	
COMPOUNDING PHARMACY, INC.	)	MDL No. 2419
PRODUCTS LIABILITY LITIGATION	)	Dkt. No. 1:13-md-2419-RWZ
	)	
	)	
	)	
This Document Relates to Suits Naming:	)	
	)	
All Cases Pending Against Saint Thomas	)	
Outpatient Neurosurgical Center And	)	
Related Defendants	)	

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PLAINTIFFS' RESPONSE TO SAINT THOMAS OUTPATIENT NEUROSURGICAL  
CENTER, LLC; HOWELL ALLEN CLINIC, A PROFESSIONAL CORPORATION;  
JOHN W. CULCLASURE, MD; AND DEBRA V. SCHAMBERG, RN, FIRST  
INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS  
PROPOUNDED TO THE PLAINTIFFS

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Pursuant to Rules 26, 33, and 34 of the Federal Rules of Civil Procedure, the Plaintiffs' Steering Committee hereby responds to the First Interrogatories and Requests for Production Propounded by the Defendants, Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Clinic"), Howell Allen Clinic, John W. Culclasure, MD, and Debra V. Schamberg, RN (collectively "Defendants" or "Saint Thomas Clinic Defendants").

**INSTRUCTIONS AND DEFINITIONS AND OBJECTIONS**

1. The term "Plaintiffs" shall mean all Plaintiffs who have pending cases against any of the Saint Thomas Clinic Defendants in active cases in the MDL.
2. The term "Plaintiffs' Counsel" shall mean the Tennessee State Chair as designated by Plaintiffs' Steering Committee pursuant to MDL Order No. 2.
3. The term "MDL" shall mean the multidistrict litigation *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*, MDL 2419, currently pending before Judge Rya Zobel in the United States District Court for the District of Massachusetts.

**INTERROGATORIES**

1. If the Plaintiffs' response to any of these Defendants' First Requests for Admissions propounded to the Plaintiffs is anything other than an unqualified admission, for each such Request for Admission, state (with identification of the corresponding Request for Admission):

- (a) All facts (not opinions) that the Plaintiffs contend support the denial or qualification of the admission.
- (b) By Bates number, if applicable, all documents, electronic and/or tape recordings, photographs, oral statements, or any other tangible or intangible thing that supports the denial or qualification of the admission.
- (c) The name and address of the custodian of all tangible things identified above.
- (d) The name and address of all persons, including consultants and experts, purporting to have knowledge or factual data upon which the Plaintiffs base the denial or the qualification of the admission.

ANSWER:

**Objection. This request is overly broad and unduly burdensome, and it requests information protected by the work product doctrine. These Defendants served 142 requests for admissions. Information supporting any denials of those requests is contained in the PSC's responses to those requests. Those responses are incorporated herein by reference.**

2. Does the PSC know of any purchaser or potential purchaser of pharmaceutical products from NECC who performed any of the due diligence the PSC alleges in paragraph 193 of the Master Complaint (reproduced below) was required before purchasing? If so, (1) identify the purchaser or potential purchaser, (2) describe the date of all due diligence, and (3) the content of the due diligence activities, conducted by each purchaser or potential purchaser.

Paragraph 193 alleges the following due diligence was required:

- a) verify whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;
- b) determine if NECC was an accredited compounding pharmacy;
- c) at least once annually, unannounced, visit NECC's corporate offices and compounding facilities and confer with NECC's corporate, pharmacy and compounding staff;
- d) determine whether NECC had any product liability lawsuits filed against it for preparations compounded;
- e) determine whether there had ever been recalls of any of NECC's compounded preparations;
- f) evaluate NECC's standard operating procedures and manuals;
- g) evaluate NECC's pharmacist technician training;

- h) evaluate NECC's policies and procedures for sterility testing;
- i) evaluate examples of batch reports for product being considered for outsourcing;
- j) evaluate examples of quality-control reports;
- k) obtain and evaluate history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;
- l) determine if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;
- m) evaluate whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;
- n) determine whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;
- o) determine whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;
- p) determine whether NECC had a policy that required validation of new or changed facilities, equipment, processes, container types, for sterility and repeatability;
- q) determine whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;
- r) evaluate NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;
- s) evaluate NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; and
- t) determine whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

ANSWER:

**Plaintiffs object to this Interrogatory to the extent that it seeks to obtain information from consulting experts or information protected by the work product doctrine. Plaintiffs are not required to disclose the opinion of any consulting or non-disclosed expert witness at this time. Plaintiffs further object to this Interrogatory since it is a contentious Interrogatory and Plaintiffs reserve the right to respond to this Interrogatory when discovery is complete as permitted under Fed. R. Civ. P. 33(a)(2). See e.g., *In re eBay Seller Antitrust Litig.*, Case No. 07-1882 JF, 2008 U.S. Dist. LEXIS 102815 (N.D. Cal. Dec. 11, 2008); *McCarthy v. Paine Webber***

*Group*, 168 F.R.D. 448 (D. Conn. 1996); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93 (E.D. Pa. 1992).

3. Identify the source(s) of the information provided in response to Interrogatory 2, including contact information for any individual and the location and Bates number(s) of any documents or electronically-stored information.

ANSWER:

**See response number 2 above.**

4. Provide the information required by Federal Rule of Civil Procedure 26(a)(1) for the Plaintiffs' claims against the following parties, even if those claims have been settled or are currently the subject of settlement discussions:

- (a) NECC;
- (b) Barry Cadden;
- (c) Glenn Chin;
- (d) Lisa Cadden;
- (e) Medical Sales Management;
- (f) Medical Sales Management SW;
- (g) Ameridose;
- (h) Gregory Conigliaro;
- (i) Douglas Conigliaro;
- (j) Carla Conigliaro;
- (k) Alaunus Pharmaceuticals;
- (l) GDC Properties Management;
- (m) Victory Mechanical Services/Victory Heating & Air Conditioning; and
- (n) ARL Bio Pharma.

ANSWER:

**Objection. This Interrogatory is overly broad, unduly burdensome, vague and calls for the production of information that is not reasonably calculated to lead to the discovery of admissible evidence. Without waiving this objection, the PSC states**

that Rule 26(a)(1) is limited to the information a party “may use to supports its claims or defenses” against a party. Since claims against the foregoing parties have settled or otherwise resolved, the PSC at this time does not intend to use any such information and will continue to rely on the previously produced Plaintiffs’ Steering Committee’s Common Initial Disclosures for Cases Pending Against Tennessee Clinics (and any supplementation thereof) to identify the information required by Rule 26(a)(1), and to the extent necessary those disclosures are incorporated herein by reference.

5. Do the Plaintiffs contend that these Defendants, or any agent or employee of these Defendants, made any statement or admission regarding alleged negligence or with respect to any allegation in the Master Complaint and/or any individual Complaint or Amended Complaint? If the answer to this question is anything other than an unqualified “No,” describe in detail who made the statement, the content of the statement or admission, the date each statement was made, to whom it was made, and the circumstances surrounding each alleged statement or admission.

ANSWER:

Plaintiffs object to this Interrogatory on the ground that it is overly broad, unduly burdensome, and vague as the term “these Defendants” is undefined and it is unclear to which Defendants this Interrogatory is intended to apply. Plaintiffs further object to this Interrogatory in that it requires Plaintiffs to review documents and statements made by Defendants. As such, discovery over the information sought by this Interrogatory can be obtained from some other source that is more convenient, less burdensome, and/or less expensive than requested, namely Defendants can review their own statements or admission in their own documents and from its own employees and agents. Accordingly, the information requested by this Interrogatory is beyond the scope of permissible discovery under Fed. Rule Civ. P. 26(b)(2)(C)(1). *See e.g. DiNapoli v. Int’l Alliance of Theatrical Stage Employees* 8, Civ. Action No. 09-5924, 2011 U.S. Dist. LEXIS 27895, 2011 WL 1004576, at \*7 (E.D. Pa. Mar. 18, 2011).

7. List each and every communication (including emails, conversations, meetings, memos, etc.) between any STOPNC or Howell Allen employee or former employee, on the one hand, and Martin Kelvas, Carmine Leffler, St. Thomas Hospital, the St. Thomas Hospital pharmacy department, Saint Thomas Health, and/or Saint Thomas Network, on the other hand, regarding compounding pharmacies, acquiring medication from 'compounding pharmacies, NECC (including its agents and representatives), and/or the acquisition of injectable steroids. For each such communication, please specify the parties to the communication, the date of the communication, the mode of the communication, and the content of the communication.

ANSWER:

**Plaintiffs object to this Interrogatory in that it requires Plaintiffs to review documents and statements made by Defendants. As such, discovery over the information sought by this Interrogatory can be obtained from some other source that is more convenient, less burdensome, and/or less expensive than requested, namely Defendants can review their own statements or admission in their own documents and from its own employees and agents. Accordingly, the information requested by this Interrogatory is beyond the scope of permissible discovery under Fed. Rule Civ. P. 26(b)(2)(C)(1). See e.g. *DiNapoli v. Int'l Alliance of Theatrical Stage Employees* 8, Civ. Action No. 09-5924, 2011 U.S. Dist. LEXIS 27895, 2011 WL 1004576, at \*7 (E.D. Pa. Mar. 18, 2011).**

8. Identify all compounding pharmacies or FDA-registered manufacturers of Depo Medrol or its generic equivalent that were producing Depo-Medrol or its generic equivalent from January 2011 to October 2012 to support the allegation that these Defendants could and/or should have purchased from another compounder or an FDA-registered manufacturer. For each compounder or manufacturer, identify the timeframe of the availability of the Depo-Medrol or its generic equivalent, the price of the Depo-Medrol or its generic equivalent during the timeframe of availability, and any distributor or supplier



selling the Depo-Medrol or generic equivalent to healthcare providers during the timeframe of availability.

ANSWER:

Plaintiffs object to this Interrogatory to the extent that it seeks to obtain information from consulting experts or information protected by the work product doctrine. Plaintiffs are not required to disclose the opinion of any consulting or non-disclosed expert witness at this time and will do so in accordance with Rule 26 and the Court's Common Discovery Order. Plaintiffs further object to this Interrogatory since it is a contentious Interrogatory and Plaintiffs reserve the right to respond to this Interrogatory when discovery is complete as permitted under Fed. R. Civ. P. 33(a)(2). *See e.g., In re eBay Seller Antitrust Litig.*, Case No. 07-1882 JF, 2008 U.S. Dist. LEXIS 102815 (N.D. Cal. Dec. 11, 2008); *McCarthy v. Paine Webber Group*, 168 F.R.D. 448 (D. Conn. 1996); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93 (E.D. Pa. 1992). Plaintiffs object to this Interrogatory in that it requires Plaintiffs to review documents and statements made by Defendants. As such, discovery over the information sought by this Interrogatory can be obtained from some other source that is more convenient, less burdensome, and/or less expensive than requested, namely Defendants can review their own statements or admission in their own documents and from its own employees and agents. Accordingly, the information requested by this Interrogatory is beyond the scope of permissible discovery under Fed. Rule Civ. P. 26(b)(2)(C)(1). *See e.g. DiNapoli v. Int'l Alliance of Theatrical Stage Employees* 8, Civ. Action No. 09-5924, 2011 U.S. Dist. LEXIS 27895, 2011 WL 1004576, at \*7 (E.D. Pa. Mar. 18, 2011).

Subject to and without waiving these or any other objection, photographs taken by Saint Thomas Clinic in 2012 inside the clinic show storage cabinet drawers stocked with Depo-Medrol made by Pfizer.

10. Identify and describe in detail the factual basis for the allegation that "GDC maintained a high degree of control over the premises leased by NECC."

ANSWER:

**The PSC objects to this request as it seeks information not reasonably calculated to lead to the discovery of admissible evidence. The allegation as alleged relates to GDC Holdings Inc. and GDC Properties Management LLC's (collectively, "GDC") possible liability under a joint enterprise liability theory. Such an allegation is not**

**relevant to any claims made by, for, or against the Saint Thomas Clinic Defendants and can have no meaningful impact on any comparative fault defense.**

11. Identify all information about NECC that the Plaintiffs contend the Defendants were required to obtain via the allegedly required minimum due diligence and describe in detail where the information was available, the reasonable steps necessary to obtain or locate it, and the basis for the Plaintiffs' belief that the information could have been obtained or located.

ANSWER:

**Plaintiffs object to this Interrogatory since it is a contentious Interrogatory and Plaintiffs reserve the right to respond to this Interrogatory when discovery is complete as permitted under Fed. R. Civ. P. 33(a)(2). See e.g., *In re eBay Seller Antitrust Litig.*, Case No. 07-1882 JF, 2008 U.S. Dist. LEXIS 102815 (N.D. Cal. Dec. 11, 2008); *McCarthy v. Paine Webber Group*, 168 F.R.D. 448 (D. Conn. 1996); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93 (E.D. Pa. 1992).**

13. Identify all persons or entities Plaintiffs believe acted wrongfully and proximately caused or proximately contributed to cause the injuries to the Plaintiffs. For each person or entity, please describe the basis of the belief that they acted wrongfully and caused or contributed to cause the injury.

ANSWER:

Plaintiffs object to this Interrogatory to the extent that it seeks to obtain information from consulting experts or information protected by the work product doctrine. Plaintiffs are not required to disclose the opinion of any consulting or non-disclosed expert witness at this time. Plaintiffs further object to this Interrogatory since it is a contentious Interrogatory and Plaintiffs reserve the right to respond to this Interrogatory when discovery is complete as permitted under Fed. R. Civ. P. 33(a)(2). *See e.g., In re eBay Seller Antitrust Litig.*, Case No. 07-1882 JF, 2008 U.S. Dist. LEXIS 102815 (N.D. Cal. Dec. 11, 2008); *McCarthy v. Paine Webber Group*, 168 F.R.D. 448 (D. Conn. 1996); *Fischer & Porter Co. v. Tolson*, 143 F.R.D. 93 (E.D. Pa. 1992).

Dated: December 23, 2014

Respectfully submitted,

/s/ J. Gerard Stranch, IV

J. Gerard Stranch, IV

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*Plaintiffs' Steering Committee and Tennessee  
State Chair*

**CERTIFICATE OF SERVICE**

I, J. Gerard Stranch, IV, hereby certify that I delivered a copy of the foregoing document via U.S. Mail and email to the attorneys listed on the attached sheet.

Dated: December 23, 2014

/s/ J. Gerard Stranch, IV

J. Gerard Stranch, IV